## REMARKS

Claims 1-12 are pending in this application. Claims 1-9, and 11-12 stand rejected for the reasons indicated in the Office Action. In response, claim 1 has been amended, and new claims 23-32 have been added. No new matter is added by these amendments. Entry of these amendments is hereby requested.

**With Respect to the Drawings, Paragraph 2 of the Outstanding Office Action:**

The drawings stand objected to because Figure 2 has a copying mark. As demonstrated in the prior Response and Amendment dated April 23, 2003, formal figures were previously submitted on March 23, 2001, and the Response and Amendment dated April 23, 2003 simply provided copies of the prior formal figure submission. New copies of the formal figures previously submitted are attached to this Response and Amendment. Withdrawal of this objection is requested.

**With Respect to the Rejections under 35 U.S.C. §102(b), Paragraph 5 of the Outstanding Office Action:**

Claims 1, 2, 4, 7 and 11 stand rejected under 35 U.S.C. §102(b) as being anticipated by Loessner et al. for the reasons discussed in paragraph 5 of the Office Action. The relevant section of the Patent and Trademark Offices reasoning is a follows:

> ...The samples were artificially contaminated with the modified living bacteria at specific areas, thus these sites qualify as a first side....Therefore Loessner et al., teach a method for evaluating whether a material will allow modified living bacteria to pass through the material or around the material or into the material comprising providing living bacteria with a first detectable signal; placing the modified bacteria on the first side of the material and detecting whether the first signal is present on the material.

According to the Loessner et al. reference, the new method discussed is:

> ...[an evaluation of] the performance of A511::*luxAB* [ previously developed] for rapid and reliable detection of *Listeria* cells in several artificially and naturally contaminated food and environmental sample, in direct comparison to the standard plating procedure. the authors reports a method for rapid detection of viable Listeria cell, based upon a luciferase reporter bacteriophage. Also, a procedure in which the lux phage is employed for a rapid enumeration of Listeria host cells in foods by using a modified

> most probable number (MPN) technique, was developed. [page 2961, col. 2, first paragraph]

According to the text of the article, artificially contamination of the samples were prepared as follows (emphasis added):

> All samples... were purchased at local retailers. Each sample (approximately 1,000 g) was aseptically divided into portions of 100 g each, packed into sterile polypropylene plastic bags, and, if applicable, immediately frozen at -70°C. One bag of each food item was then thawed and tested for the presence of listeria (i.e. natural contamination) by the IDF procedure as outlined below. Samples that were negative by this method were considered for trials with artificially contaminated foods. **Remaining bags were then thawed and homogeneously mixed with 1 ml each of appropriate decimal dilutions of a log-phase culture of *L. monocytogenes* Scott A (including uninoculated controls), to obtain the initial contamination rates as realistic conditions.** After that, they were analyzed in parallel by the standard IDF culture method and the luciferase reporter phage assay as described below. [page 2962, column 2, paragraph 2]

Claim 1 as pending in the present invention recited the following limitation:

> b) placing the modified living bacteria on a first side of the material being evaluated;

As quoted above, the modified bacteria disclosed in the Loessner et al. reference are mixed HOMOGENEOUSLY throughout the sample to be tested. Contrary to the assertion of the Patent and Trademark Office, the samples were NOT artificially contaminated with the modified living bacteria at SPECIFIC areas. In fact, it would be impossible to contaminate the samples at less specific areas than HOMOGENEOUSLY mixing them throughout the sample. Claims 2, 4, 7 and 11 depend on claim 1. Therefore, the Applicant requests that the rejection of claims 1, 2, 4, 7 and 11 under 35 U.S.C. §102(b) be withdrawn.

**With Respect to the Rejections under 35 U.S.C. §103(a), Paragraph 6 of the Outstanding Office Action:**

Claims 1-8 and 11 stand rejected under 35 U.S.C. §103(a) as being obvious over United States Patent 5,736,351 to Miller in view of Contag et al. With respect to Contag et al., the Patent and Trademark Office stated:

> The authors [of Contag et al.] demonstrated that bioluminescent light is transmitted through the tissue of an animal infected with that pathogen, thus allowing localization of the bacteria to specific body sites, which qualify as different sides of a material. [page 6, paragraph 2]

Contag et al. discloses a method for detecting bacterial pathogens in a living host by inoculating the host intraperitoneally with a modified pathogen and determining the distribution of the pathogen after inoculation. The Applicant respectfully traverses the contentions of the Patent and Trademark Office above for several reasons. First, since the route of inoculation was intraperitoneal injection, it is not possible to determine the route of spread of the pathogen. That is both skin, subcutaneous tissue and, presumably, the vascular system among other tissues was breeched in such a procedure, besides the possible breech of the gastrointestinal tract itself. There is no indication in the cited reference of how the spread of the pathogen occurs. Thus, it is not possible to say that the pathogen actually traversed a particular tissue rather then entered the tissue through vascular spread or by other mechanisms.

Second, while it is true that the pathogen distributes in various locations of the living host, the material traversed or entered is not discernable contrary to the assertion of the Patent and Trademark Office. The gastrointestinal tract of a living organism is not a material, with consistent properties--it is a living tissue, as will be understood by those with skill in the art with reference to the disclosure. If the Patent and Trademark Office persists in its contentions regarding Contag et al., the Applicant requests that the Patent and Trademark Office identify the tissue and the teaching of route of distribution from the cited reference itself.

Additionally, the present invention is directed to natural and artificial materials that can implanted in humans and animals during the treatment of injuries, conditions and diseases. See for example, page 4, lines 14-28, and page 9, lines 17-19. The Contag et al. reference is simply non- analogous art that one of ordinary skill in the art would not use to locate a solution to the problem addressed by the present invention. A method of spread of a pathogen through a complete living organism is not likely to be relevant to testing materials for susceptibility to contamination or colonization. In order to more clearly distinguish the present invention over

the Contag et al. reference, claim 1 has been amended to include the limitation "where the material is non-living."

With respect to United States Patent 5,736,351 to Miller, this reference does not appear to disclose any method of evaluating whether a material will allow modified living bacteria to pass through the material or around the material or into the material, only a method of determining whether a surface is contaminated, and the Patent and Trademark Office has not alleged that it does. Therefore, the teaching of the United States Patent 5,736,351 to Miller does not cure the deficiency identified in Contag et al., above, and the combination of the two references does not establish a prima facie case of obviousness.

Claim1-8 and 11 depend on claim 1. Therefore, the Applicant requests that the rejection of claims 1-8 and 11 under 35 U.S.C. §103(a) be withdrawn.

**With Respect to the Rejections under 35 U.S.C. §103(a), Paragraph 7 of the Outstanding Office Action:**

Claims 9 and 12 stand rejected under 35 U.S.C. §103(a) as being obvious over United States Patent 5,736,351 to Miller in view of Contag et al. and further in view of United States Patent 5,814,331 to Holen. Claims 9 and 12 depend on claim 1. As discussed above, claim 1 is believed to be in condition for allowance. Therefore, this rejection is moot.

**With Respect to New Claims 23-32:**

Claims 23-32 have been added by this Response and Amendment. Claim 23 contains all of the limitations of previously presented claim 10 and its underlying claims 1 and 3. As claim 10 was found to be free of prior art, new claim 23 is believed to be patentable. Claims 24 -32 correspond to previously presented claims 2, 4-9 and 11-12, and depend on new claim 23. Therefore, claims 23-32 are believed to be patentable.

**CONCLUSION**

The Applicants believe that all pending claims, claims 1-12, and 23-32 are now in condition for allowance and an indication of such is requested. If, however, there remain

any issues which can be addressed by telephone, the Examiner is encouraged to contact the undersigned.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication to Deposit Account No. 19-2090.

Respectfully submitted,

SHELDON & MAK
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